UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,345	08/01/2003	Victor Selig	ST8630US	3729

22203 7590 08/30/2006

KUSNER & JAFFE
HIGHLAND PLACE SUITE 310
6151 WILSON MILLS ROAD
HIGHLAND HEIGHTS, OH 44143

EXAMINER	
JOHNSON, EDWARD M	

ART UNIT	PAPER NUMBER
1754	

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,345	SELIG ET AL.	
	Examiner	Art Unit	
	Edward M. Johnson	1754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 4-6 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Halstead et al. US 6,919,057.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 4, Halstead '057 discloses a method of cleaning and disinfection of devices comprising:

a) placing the items into a rack within a container having sealing members, a cavity, and a gasket assembly comprising fluid access ports in the form of slots (abstract, Figures),

b) placing the container into a reprocessor (abstract),

c) pumping a reprocessing liquid through the slots to contact all surfaces of the device with the liquid (abstract),

d) removing the rack and container from the reprocessor (see column 11, lines 31-34), which would inherently store the items therein until removed.

When the examiner has reason to believe that the functional language asserted to be critical for establishing novelty in claimed subject matter may in fact be an inherent characteristic of the prior art, the burden of proof is shifted to Applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied upon. *In re Fitzgerald* et al. 205 USPQ 594. As a practical matter, the Office is not equipped to manufacture or obtain products and make resulting comparisons with the claimed invention. Where, as here, the burden has been shifted to applicant, it is appropriate to make a rejection based upon §102 as well as §103.

Regarding claim 5, Halstead '057 discloses liquid (abstract).

Regarding claim 6, Halstead '057 discloses a heated air-drying step (see column 12, lines 10-13).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halstead '057.

Regarding claim 1, Halstead '057 discloses a method of cleaning and disinfection of devices comprising:

a) placing the items into a rack within a container having a cavity and a gasket assembly comprising fluid access ports in the form of slots (abstract, Figures),

b) placing the container into a reprocessor,

c) pumping a reprocessing liquid through the slots to contact all surfaces of the device with the liquid (abstract),

d) removing the rack and container from the reprocessor (see column 11, lines 31-34), which would store the items therein until removed.

Halstead fails to disclose causing the container to assume the closed position at removal.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to cause the container of Halstead to assume the closed position because Halstead discloses a leak test after reprocessing to ensure an endoscope is not damaged during reprocessing (see column 12, lines 27-30), which would motivate an ordinary artisan to close to container upon the disclosed removal of the container to advantageously avoid damage of the item to be reprocessed.

Regarding claim 2, Halstead '057 discloses removing the rack and container from the reprocessor (see column 11, lines 31-34), which would store the items therein until removed.

Regarding claim 3, Halstead '057 discloses a heated air-drying step (see column 12, lines 10-13).

Response to Arguments

5. Applicant's arguments filed 7/10/06 have been fully considered but they are not persuasive.

It is argued that Halstead et al. '057 discloses... automated reprocessor. This is not persuasive because Halstead discloses

the container having sealing members (see Fig. 3 and column 6, lines 1-7). It is also noted that apparatus limitations are not generally given undue weight in method claims.

It is argued that Halstead et al. '057 does not teach... as required by claim 4. This is not persuasive because Applicant appears to admit that the container is "closed" when an endoscope is placed within, which would be considered to be a normally closed position rather than an abnormally closed position. Further, it is again noted that apparatus limitations are not generally given undue weight in method claims.

It is argued that the Examiner states that "Halstead discloses... to be reprocessed." This is not persuasive because the Examiner has not taken the position that Halstead specifically "discloses" the claimed step, which would essentially have been a 102 rejection. Rather, it is considered that it would have been obvious to one of ordinary skill in the art at the time the invention was made to cause the container of Halstead to assume the closed position because Halstead discloses a leak test after reprocessing to ensure an endoscope is not damaged during reprocessing (see column 12, lines 27-30), which would motivate an ordinary artisan to close to container upon the disclosed removal of the container to advantageously avoid damage of the item to be reprocessed.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward M. Johnson whose telephone number is 571-272-1352. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley S. Silverman can be reached on 571-272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Edward M. Johnson
Primary Examiner
Art Unit 1754

EMJ